



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0223]

Humanitarian Device Exemption Program; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Humanitarian Device Exemption Program." This guidance concerns the humanitarian device exemption (HDE) program as a whole and, among other topics, it explains the criteria FDA considers to determine if "probable benefit" has been demonstrated as part of the Agency's decision-making process regarding marketing authorization for a humanitarian use device (HUD). The guidance also reflects recent amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) that affect the HDE program and answers common questions that we receive about the program.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2014-D-0223 for "Humanitarian Device Exemption Program." Received comments will be placed in the

docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Humanitarian Device Exemption Program" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request. FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993-0002, 301-796-6524; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA developed this guidance to clarify to industry and FDA staff the current review practices for the HDE program. This guidance answers common questions about the HDE program and responds to a requirement in the 21st Century Cures Act (Cures Act) (Pub. L. 114-

255) to define the criteria for establishing "probable benefit" as that term is used in section 520(m)(2)(C) of the FD&C Act (21 U.S.C. 360j(m)(2)(C)).

This guidance reflects recent amendments to the FD&C Act that affect the HDE program. Specifically, section 3052 of the Cures Act modified the eligibility for an HDE by increasing the threshold number of patients affected by the disease or condition that a HUD is designed to treat or diagnose to "not more than 8,000 individuals in the United States." Further, section 3056 of the Cures Act removed the requirement that institutional review committees, i.e., institutional review boards (IRBs), that supervise the clinical testing of HUDs or approve the use of HUDs in clinical care, be local. Additionally, the FDA Reauthorization Act of 2017 (Pub. L. 115-52) amended section 520(m) of the FD&C Act to provide that the use of a device under an HDE at a facility to treat or diagnose patients may be approved by an IRB or an appropriate local committee. Previously, section 520(m)(4) of the FD&C Act only allowed an IRB to perform this function.

FDA considered comments received on the draft guidance that appeared in the *Federal Register* of June 13, 2018 (83 FR 27614). FDA revised the guidance as appropriate in response to the comments. This guidance supersedes "Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff; Humanitarian Device Exemption (HDE) Regulation: Questions and Answers," issued July 8, 2010 (available at: <https://www.fda.gov/media/74307/download>).

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the Humanitarian Device Exemption Program. It does not establish any rights for any person and is not binding on

FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

### III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov> or <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Persons unable to download an electronic copy of "Humanitarian Device Exemption Program" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 17040 and complete title of the guidance in the request.

### IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR Part, Guidance, or FD&C Act Section	Topic	OMB Control No.
807, 812, 814	Acceptance of Data from Clinical Investigations for Medical Devices	0910-0741
814	Pediatric Uses of Devices	0910-0748
814, subparts A through E	Premarket Approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078

"De Novo Classification Process (Evaluation of Automatic Class III Designation)"	De Novo classification process	0910-0844
803	Medical Devices; Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting	0910-0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073
520(m) of the FD&C Act	Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements	0910-0661
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910-0755
56	Institutional Review Boards	0910-0130
10	Administrative Practices and Procedures	0910-0191
54	Financial Disclosure by Clinical Investigators	0910-0396

Dated: September 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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